Quality Assurance and Manufacturing Systems

As the Defense Acquisition Life Cycle progresses, it becomes readily apparent that Acquisition Professionals must possess an in-depth understanding of the individual processes that lend themselves to the overall Acquisition Life Cycle. These processes lend significance to the fielded weapon system from the contractor's perspective as well as from the perspective of the Department of Defense.

Recent years have seen major changes in the way we, as a manufacturing community, view the acquisition of defense systems. The majority of these changes have come in the way we manage individual processes within the government as well as the private sector. We see a team approach as the most appropriate method in the management of processes

While this lesson is entitled "Quality Systems and Post-Production Issues" the goal, ultimately, is to acquaint you with those processes that have traditionally been labeled "Contract Surveillance". Quality and manufacturing concepts and practices are also applicable and very significant early in the Acquisition life cycle. Both should be primary areas of consideration as early as Phase I of the Acquisition life cycle. Specifically, in relation to risks associated with technology, manufacturing and cost, these Quality and Manufacturing concepts should manifest themselves in Phase II and become more robust as the system matures through Engineering and Manufacturing Development, and finally into the full scale production contract.

DoD Deskbook Extracts

In an effort to emphasize the changes in concepts and philosophies within the Department of Defense Acquisition Community, DoD has rewritten the DoD 5000 series documents. The Department of Defense Directive (DoDD) 5000.1 has been rewritten to establish a more disciplined management approach for Defense Acquisition. DoDD 5000.1 articulates general principles to guide all Defense Acquisition Programs. These principles are organized into three broad categories:

1. Translating operational needs into stable, affordable programs
2. Acquiring quality products
3. Organizing for efficiency and effectiveness

DoD 5000.2-R establishes mandatory procedures for Major Defense Acquisition Programs (and selected other programs as specified in the Regulation). The Regulation is organized into six parts that focus on major management and programmatic elements of the acquisition process, such as program definition, program structure, and program design. The parts of the Regulation are:

1. Acquisition Management Process
2. Program Definition
3. Program Structure
4. Program Design
5. Program Assessments and Decision Review
6. Periodic Reporting

The USD (A&T) is responsible, through the Secretary of Defense, to the President and the Congress for meeting the Department's commitment to the projected cost, schedule, and performance of material acquisition programs. The DOT&E is responsible for determining that systems are operationally effective, suitable, and survivable prior to fielding. DoDD 5000.1 and DoD 5000.2-R establish a disciplined yet flexible management approach to assist these officials in fulfilling their responsibilities.

Using DoD 5000.2-R as a model we will begin to place into perspective the Quality Assurance and Manufacturing Systems as well as specific processes that will ultimately field an acceptable weapon system. DoD 5000.2-R, par. 4.3.1, Manufacturing and Production states the DoD policy relative to producibility of design and manufacturing processes. DoD 5000.2-R part 4.3.2 requires that the Program Manager allow the contractor a great deal of flexibility in their definition of a quality system that meets the program requirements. As a minimum a Quality Management System should require:

1. Establishment of capable processes
2. Monitoring and control of critical processes and products
3. Establishment of mechanisms for feedback of field product performance
4. Implementation of an effective root cause analysis
5. Continuous process improvement

In addition to the requirements delineated in DoD 5000.2-R, the policy and guidance provided in the Defense Acquisition Deskbook is essential to acquiring an understanding of the current DoD posture regarding Quality and Manufacturing Systems. The Defense Acquisition Deskbook provides both mandatory direction and discretionary practices. The following is an excerpt from the "Deskbook", Quality Section 2.6.E, and Supplemental Guidance from the Office of the Undersecretary of Defense for Acquisition and Technology (USD (A&T)).

Quality products and services are fundamental to successful military operations, as well as to successful system development and production. The quality of products, or services is determined by the extent they meet (or exceed) requirements and satisfy customer(s) at an affordable cost. The goal of an effective acquisition program is to acquire goods and services that meet or exceed DoD requirements, better, faster, and at less cost. The emphasis and practices to achieve quality have evolved dramatically in recent years. The major shift in defense acquisition is to emphasize development of quality products through design of the product and its associated processes.

Mandatory Direction

Federal Acquisition Regulation (FAR), Part 46, Quality Assurance
DoD FAR Supplement (DFARS), Part 246, Quality Assurance
DoD Directive 5000.1, Defense Acquisition, Section D, Policy, Paragraph 2, "Acquiring Quality

DoD Instruction 5000.2, Mandatory Procedures for Major Defense Acquisition Programs (MDAPs) and Major Automated Information System Acquisition Programs (MAISs), Part 4.3.2, "Quality"

Third Party Quality System Registration. Contracting officers shall not require third party quality system registration to ANSI/ASQ-Q9001, Q9002, or Q9003 per DoD 5000.2. The presence or absence of a registered quality system shall not be a factor in determining the extent of quality system surveillance at the prime and subcontractor levels. In no case should the Government surrender its rights under the standard inspection clause. The existence of a registered quality system should not exempt the contractor from any contractual design, performance, or quality responsibilities. The determination of the adequacy of a contractor's quality system in meeting contract requirements is the responsibility of the military buying activities and contract administration services (CAS) activities.

Discretionary Practices

DoD-wide Established Practices

GENERAL GUIDANCE

Traditional quality management systems have typically focused on the identification and control of hardware that fails to meet specified requirements. Although preventing nonconforming material from reaching the hands of the customer is a critically important function, the traditional quality assurance approach suffers from a number of drawbacks. Foremost among these is that identification and control of defects have proven to be much more costly than preventing their occurrence in the first place. Secondly, inspection and test -- even when performed on a 100 percent basis -- often fail to identify all existing non-conformities. Lastly, the use of end item inspection as a principle means of determining product acceptability has frequently led to the perception that workers who perform such inspections and tests -- rather than those who design, fabricate, assemble and maintain the product -- are responsible for product quality.

Two major policy changes have dramatically changed the DoD perspective on quality:

-- USD (A&T) memorandum of February 14, 1994 entitled: Use of Commercial Quality System Standards in the Department of Defense requires Program Managers to give contractors the flexibility to identify their own quality system and management requirements and encourages use of a single quality process in a contractor's facility.

Achievement of quality requires an effective quality management process in conjunction with effective business and technical practices. Achievement requires engineering and manufacturing practices that emphasize robust design along with enterprise-wide process maturity through continuous process improvement efforts. Benefits include first time pass quality, decreased cycle time, as well as reductions in rework, engineering changes, and inspections. These benefits translate into improved affordability and reduced production transition risk. A basic quality management system should be a requirement of the contract, and should adhere, at a minimum, to the 20 elements described in ANSI/ASQ - Q9001. A basic quality management system relies on assessment of the contractor's quality management process, process controls, inspection, and test and is primarily focused on controlling and detecting manufacturing defects.

-- SECDEF memorandum, dated May 10, 1995, entitled Use of Integrated Product and Process Development and Integrated Product Teams in DoD Acquisition, provides the framework for achieving quality products through integrated product and process development. We now

believe that quality products are best achieved through integrated development of the product and its associated manufacturing and support processes. Quality must be an integral part of the work of integrated product teams and implementation of IPPD.

Unlike the traditional quality approach to obtaining quality product which focused on conformance, product quality is now viewed as an attribute that is controlled by the engineering/design and business processes, as well as the maturation of the associated manufacturing/production process.

Achievement of quality must be the underlying objective in all program matters including source selection, contract administration and supplier management, risk management, engineering, manufacturing and testing processes, etc. Quality is the product of effective implementation of these processes. While the need to determine the conformance of the product through end item inspection will probably continue as long as taxpayers' dollars are being spent, the focus on how to achieve quality has shifted. To achieve the levels of quality required in today's marketplace, the focus now is on the processes. Company's now must ensure the appropriate use of the very best engineering, manufacturing, and management practices.

An effective quality system focuses on the following:

(1) Quality of Design. The effectiveness of the design process in capturing the operational, manufacturing and quality requirements and translating them into robust design requirements that can be manufactured (or coded) and supported in a consistent manner.

(2) Conformance to Requirements. The effectiveness of the design and manufacturing functions in meeting the product requirements and associated meeting tolerances, process control limits, and target yields for a given product group.

(3) Fitness for Use. The effectiveness of the design, manufacturing and support processes in delivering a system that meets the operational requirements under all required operational conditions.

(4) Cost. The cost of the product and how the design, manufacturing, and management processes affect unit and life cycle costs.

The following guidelines for establishing and maintaining an effective quality management program are discussed below:

1. Application and use of commercial quality management standards
2. Encouraging use of a single quality process in a contractor’s facility
3. Recognizing and encouraging the appropriate use of practices and tools that lead to acquiring a quality product
4. Establishing and implementing efficient and effective oversight.

APPLICATION AND USE OF COMMERCIAL QUALITY STANDARDS

Policy and guidance on the application of quality standards is provided in the FAR Part 46; DFARS Part 246; and SECDEF memorandum of June 29, 1994, entitled “Specifications and

Standards - A New Way of Doing Business"; and USD (A&T) memorandum of December 8, 1995, titled "Single Process Initiative".

DoD organizations are authorized to use ANSI/ASQ-Q9000, and/or the ISO 9000 series standards in all new contracts, and follow-on work for existing programs, provided contractors are given the flexibility to respond with their own equivalent quality systems. The ANSI/ASQC documents covered under ANSI/ASQC-Q9000 represent different levels of quality requirements outlined as follows:

ANSI/ASQ-Q9001	"Quality Systems - Model for Quality Assurance in Design/Development, Production, Installation, and Servicing"
ANSI/ASQ-Q9002	"Quality Systems - Model for Quality Assurance in Production and Installation, and Servicing"
ANSI/ASQ-Q9003	"Quality Systems - Model for Quality Assurance in Final Inspection and Test"

ANSI/ASQ-Q9001, Q9002 and Q9003 are the U.S. equivalents and equal to the international quality standards ISO 9001, ISO 9002, and ISO 9003, respectively. The guidance herein applies equally to both the ANSI/ASQ-Q9000 series and the ISO 9000 series documents.

The elements of ANSI/ASQ-Q9000 represent a framework for a basic quality system, however, they should not be viewed as the only commercial quality specifications available, nor the most effective basic quality system requirements. Many other industry quality standards (i.e., the auto industry's QS9000, Motorola's Six Sigma, and Boeing's D1-9000) exist and are potentially more effective than the ISO or ANSI quality standards. The DoD policy, then, is to cite the DoD requirement with the words "or equivalent" to allow offerors the flexibility to propose their own equivalent or better quality system. Quality systems that satisfy DoD acquisition needs should be recognized whether they are modeled on military, commercial, national, or international standards.

The ANSI/ASQ-Q9000 standards have a number of limitations in that they address the elements of a contractor's quality system, but do not address the application of such a system to the products or processes as related to a particular contract.

In implementing this guidance in competitive request for proposals (RFPs), buying activities may consider the following language for performance based statement of work (SOW) the statement of objectives (SOO), Section L, and Section M. (While the sample language that follows is structured for a development phase RFP, it is adaptable for production phase RFPs.)

Suggested SOW/SOO language for a quality system requirement. "The contractor shall implement a quality system that satisfies the program objectives and is modeled on ANSI/ASQ-Q9001 or an equivalent quality system."

Suggested Section L language. "Offerors shall propose a quality system that satisfies program objectives and is modeled on ANSI/ASQ-Q9001, or an equivalent quality system." Offerors shall:

a) Describe the proposed quality system, explaining how it will be applied to reduce program risk, and specifically addressing (as a minimum) the quality system's role in design and development (with particular emphasis on addressing key product characteristics), manufacturing planning, and key program events.

b) Provide a relational matrix comparing, in detail, the proposed quality system with each of the elements of ANSI/ASQ-Q9001"

Suggested Section M language. "The offeror's quality approach will be evaluated based on its effective:

a) Application to all appropriate aspects of the program
b) Coordination with other functions
c) Integration into overall program planning; and
d) Contribution to reduction of program risk."

The offeror's ability to satisfy the quality management system objectives should be assessed in source selection and continuously monitored after contract award. The 20 elements of ANSI/ASQ-Q9000 formulate the baseline for review and approval of a contractor's quality management process. In reviewing contractor quality management systems, particular emphasis should be given to management responsibility, supplier control, corrective and preventive action, and internal audit.

USE OF A SINGLE QUALITY PROCESS IN A CONTRACTOR'S FACILITY

DoD policy on the use of single processes in a contractor's facility is provided in SECDEF memo, dated December 6, 1995, subject: Common Systems/ISO 9000/Expedited Block Changes, and USD (A&T) memo, dated December 8, 1995, subject: Single Process Initiative. These memos were intended, in part, to expedite the shift from military quality standards to commercial (ISO/ANSI/ASQ) standards. The goal is to preclude requiring, in a single facility, multiple quality, business or technical processes designed to accomplish the same purposes. The implementation of the single process initiative has coincided with the formulation of local management councils (consisting of representatives of the buying activity, ACO, DCAA and contractor) at effected contractor facilities to assess process issues. Contractor proposed implementation will be initiated based on submission of concept papers. The PM should support contractors' efforts to implement a single quality management system throughout their facilities.

The above policy represents a major DoD initiative allowing industry to be more efficient, improve quality and reduce overall cost of acquiring products.

RECOGNIZING AND ENCOURAGING THE APPROPRIATE USE OF ENGINEERING AND MANUFACTURING PRACTICES

As previously stated, the prevention of defects, rather than the detection of defects, is the goal of the Department. Defect prevention practices is a term identified by some in industry to mean the appropriate, timely application of engineering, manufacturing, and management practices that emphasize the prevention of defects, rather than detection of defects. Defect prevention practices need to be defined within an organizational context, not as a stand-alone list. What may be appropriate for a design, or low rate production enterprise, may not be for a commodity manufacturer, and vice versa. Some of the more commonly used practices in industry include:

1. Identification and control of key characteristics
2. Design to manufacturing process capability
3. Design for manufacturing and assembly (DFMA)
4. Robust design
5. Geometric Dimensioning and Tolerancing
6. Process variability reduction, of stable, capable manufacturing processes as the basis for product acceptance
7. Control of variation in the measurement system
8. Failure reporting analysis and corrective action system
9. Continuous improvement
10. Other tools such as use of modeling and simulation, CAD/CAE/CAM, and use of maturity models, etc.

While the requirement for a basic quality system is incorporated into DoD contracts, the contractor's ability to document and implement these practices and tools is fundamental to achieving quality products. Here, we'll define quality products as those that meet the users' requirements at an affordable cost.

(Deskbook Ends Here)

DoD has authorized the use of ANSI/ASQ-Q9001 and Q9002. The 20 elements of the ISO 9001/Q9001 form the basis for an acceptable quality assurance system. Highlights of the ISO 9001 elements follow:

4.1 Management Responsibility

- Quality policy is the responsibility of an executive manager.
- The responsibility and authority of personnel engaged in prevention of nonconformity, problem identification, and resolution shall be defined and documented.
- Executive management shall appoint a manager responsible for the quality system.
- Quality system performance reviews will be at defined intervals to ensure continual suitability and effectiveness.

4.2 Quality System

- Quality manual should be structured according to ISO-10013.
- Procedures shall be documented to reflect this standard.
- Quality plans shall be prepared for products, projects or contracts that identify process, equipment, resources, etc., to ensure design intent meets purchaser requirements and necessary inspections and tests are conducted.

4.3 Contract Review

The supplier shall establish and maintain documented procedures for contract review and for the coordination of these activities.

4.4 Design Control

The supplier shall establish and maintain documented procedures to control and verify the design of the product in order to ensure that the specified requirements are met. Some specific actions that shall take place:

- Design and development planning
- Organizational and technical interfaces
- Design input
- Design output
- Design review
- Design verification
- Design validation
- Design changes

4.5 Document and Data Control

The supplier shall establish and maintain documents and data that relate to the requirements of the International Standard including, to the extent applicable, documents of external origin such as product and process standards and customer drawings.

4.6 Purchasing

The supplier shall maintain a documented procedure to ensure that purchased product conforms to specified requirements. Areas of specific actions are:

- Evaluation of subcontractors
- Purchasing data
- Verification of purchased product

4.7 Control of Customer Supplied Product

The supplier shall establish and maintain documented procedures for control of verification, storage and maintenance of customer-supplied product provided for incorporation into the supplies or other related activities.

4.8 Product Identification and Traceability

Where appropriate, the supplier shall establish and maintain documented procedures for identifying the product by suitable means from receipt and during all stages of production, delivery and installation.

4.9 Process Control

The supplier shall identify and plan the production, installation, and servicing processes that directly affect quality and shall ensure that these processes are carried out under controlled conditions.

4.10 Inspection and Testing

The supplier shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met. The required inspections and testing, and the records to be established shall be detailed in the quality plan or documented procedures. Major areas to consider are:

- Receiving inspection and testing
- In-process inspection and testing
- Final inspection and testing
- Inspection and test records.

4.11 Control of Inspection, Measuring and Test Equipment

The supplier shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by the supplier to demonstrate the conformance of product to specified requirements. Inspection, measuring and test equipment shall be used in a manner that ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

4.12 Inspection and Test Status

The inspection and test status of product shall be identified by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and test performed.

4.13 Control of Nonconforming Product

Supplier establishes and maintains documented procedures to ensure nonconforming products are prevented from use. This control provides identification, documentation, evaluation, segregation, disposition, and notification to concerned functions; and the review and disposition of nonconforming product.

4.14 Corrective and Preventive Action

- Corrective action considerations
    - Effective handling of complaints and reports of nonconformity
    - Investigation of causes
    - Determination of corrective action needed to eliminate causes
    - Application of controls to ensure corrective action is taken and that it is effective
- Preventive action considerations:
    - The use of appropriate sources of information
    - Determination of steps to be taken for prevention
    - Initiation of preventive action
    - Ensure relevant information on action is taken

4.15 Handling, Storage, Packaging, Preservation, and Delivery

The supplier shall establish and maintain documented procedures for handling, storage, packaging, preservation, and delivery of product.

- Handling to prevent damage or deterioration.
- Storage in designated storage areas or stockrooms, including methods for authorizing receipt and dispatch.
- Packaging control and marking processes to ensure conformance to specified requirements.
- Preservation and segregation of product when product is under supplier's control.
- Delivery including protection of quality of product after final inspection and test.

4.16 Control of Quality Records

The supplier shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

4.17 Internal Quality Audits

- The supplier shall establish and maintain documented procedures for planning and implementing internal quality audits to verify whether quality activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.
- Internal quality audits shall be scheduled and shall be carried out by personnel independent of those having direct responsibility for the activity being audited.
- The results shall be recorded.
- Follow-up audit activities shall verify and record implementation and effectiveness of the corrective action taken.

4.18 Training

The supplier shall establish and maintain documented procedures for identifying training needs and provide training.

4.19 Servicing

Where specified as requirement, the supplier shall establish and maintain documented procedures for performing, verifying and reporting that the serving meets the specified requirements.

4.20 Statistical Techniques

- Supplier shall identify the need for statistical techniques required for establishing, controlling and verifying process capability and product characteristics.
- Establish and maintain documented procedures to implement and control the application of the statistical techniques identified.

The Defense Contract Management Command (DCMC) by the issuance of the October 26, 1995 letter by Major General Drewes, USAF, has also recognized ISO 9000 and the associated registration process. An abstract of this letter follows:

DCMC/CAO is to perform ISO 9000 audits on selected contractors if the standard(s) is on contract or if the contractor is moving toward implementation of ISO 9000. Audit results are only revealed to the customer (PMO, Buying Command) and the contractor.

Furthermore, DCMC/CAO will:

- Perform full audits when requested by the buying command or if no information is available as to the adequacy of a contractor's quality system.
- Verify third party registration data, including past audits and first and second party audits.
- Accompany the third party auditors if concurred with by the contractor. When participating with a audit, the CAO auditors shall normally audit the following elements of the quality system:
    - Management responsibility
    - Corrective and preventive actions
    - Internal audits.

DCMC will issue statements of qualifications. Auditors will be trained in ISO auditing practices and customers and contractors will be invited to participate in the audits.